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EXAMINER	
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ART UNIT	PAPER NUMBER
2505	38

DATE MAILED: 02/14/97

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).
- ☒ Applicant's response to the final rejection, filed 25 Nov 1996 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. ☐ They raise new issues that would require further consideration and/or search. (See Note).
- c. ☐ They raise the issue of new matter. (See Note).
- d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: 11-15, 17-19, 22-26, 35, 43-53

Claims objected to: _____

Claims rejected: 1, 6, 7, 33, 34, 36-42, 54, 55

However;

- ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because of the reasons set forth in the attached discussion
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

1. An Office action requiring a response was mailed 16 May 1996; the statutory six month period for response thus ended 16 November 1996. A response was filed 25 November 1996 with a three month extension of time and a certificate of mailing dated 18 November 1996. 16 November 1996 was a Saturday, so a paper filed with a certificate of mailing dated 18 November 1996, the following Monday, was timely. Also filed 25 November, also with a certificate of mailing dated 18 November 1996, was a notice of Appeal.

Due to a delay in the Office in matching these papers to the file, the application was mistakenly held to be abandoned for failure to respond to the Office action mailed 16 May 1996. As a response and a notice of appeal had in fact been timely filed, the application was not, and is not now, abandoned. An confusion resulting from this delay is regretted.

2. The Office action mailed 16 May 1996 was a final action; see section 13 of that action. Apparently through oversight the finality of the action was not indicated on the cover sheet (PTOL-326). Any confusion or delay resulting from this oversight is regretted.

3. The amendment to claim 55 in the paper filed 25 November 1996 has been entered, but does not overcome the rejections of that claim.

4. Claims 54 and 55 stand rejected under 35 USC § 112, first paragraph as not being supported by the disclosure as filed. The response filed 25 November 1996 argues that the phrase "the layers of skin and fat which cover muscle tissue" in the specification, page 1, lines 22-23 "does indeed encompass the 'living tissue' of a patient." While it may be correct that the instant specification may contain a disclosure broad enough to not exclude a medical application, the question is here is whether the specification actually discloses a particular medical application of the disclosed probe to support claiming such a medical application; the mere fact that the disclosure does not exclude a medical application is not support for claiming a medical application. It appears that the specification does not disclose a medical application with the required specificity to allow such an application to be specifically claimed as in claims 54 and 55.

5. Claims 54 and 55 stand rejected under 35 USC § 102(e) as being anticipated by Hirao et al (US 5,057,695).

Applicant has submitted, with the paper filed 25 November 1996, a declaration under 37 CFR § 1.131 to establish a date of invention prior to the effective date of the Hirao reference. This declaration is not acceptable.

The declaration does not specifically relate to what is claimed; for example, the declaration states only that "the principle purpose of the probe was to develop two or more independent signals ... for further processing". Claim 54 requires

more than merely "further processing", but rather "providing a quantitative measure of a substance in living tissue, the quantitative measure being dependent of the ratio of the first and second output signals." Claim 55 also requires more than merely "further processing", it requires "producing a quantitative measure of said substance in said living tissue by determining the ratio of the intensities of said electromagnetic radiation detected by said first and second radiation detection means". Thus the declaration does not allege that the named inventor was in possession of the subject matter of claims 54 and 55 "prior to December 15, 1989".

Also, the declaration does not contain any evidence to support the allegations therein; the declaration is thus only hearsay and conclusionary. The declaration mentions "several sketches", but copies of these sketches are not included. Actual evidence of possession by the named inventor prior to the effective date of the reference is needed. See 37 CFR § 1.131(b), which requires in part "[o]riginal exhibits of drawings or records, or photocopies thereof, must accompany and form a part of the affidavit of declaration".

6. The response filed 25 November 1996 also contains two declarations under 37 CFR § 1.132, directed, apparently, to all of the rejected claims. These declarations are not persuasive.

The declaration by Harry Shamoon, MD, relates to the solution to a long felt need by the claimed invention. The declaration clearly relates to "a dual-ring

device". Thus the declaration clearly does not relate to claims 54 and 55, which do not limit the shape of the detection areas to "a dual-rings device". Also, the relevance to the other rejected claims is at best questionable, as it appears none of the claims are, or are intended to be, limited to a dual-ring arrangement; the language of the claims, which includes such language as the surface areas being "extended in length" appears to be broader than the "dual rings" discussed in the declaration.

The declaration by Harry Shamon, MD, relates to the use of a "dual-ring arrangement" in the measurement of blood glucose; the instant specification contains no disclosure relating to the measurement of blood glucose by the claimed apparatus. It is noted that even if, *arguendo*, the method for measuring blood glucose levels discussed in the declaration were new and unobvious for the reasons of the declaration, the device itself could logically and legally be neither novel nor unobvious; the method of the declaration could be a new use for an old device. Thus this declaration, as it depends for its arguments on undisclosed utility, is not relevant to the claims in this application.

7. The declaration under 37 CFR § 1.132 by Karl Norris is also not persuasive. The discussion of the Borsboom reference in the declaration appears to be in error. The declaration, page 3, second paragraph, includes the statement the reference "measures the energy which is reflected or backscattered into the illumination

fiber as a second detection site, However, this energy is predominately returned from the surface of the sample. It exhibits little of no absorption resulting from interaction with the interior volume of the sample." This passage appears to be incorrect. The central "fiber" of Borsboom, which is use in part for providing the illumination, is not a single fiber, but is rather a fiber bundle; the illumination and the detection in this central fiber bundle occur through separate individual fibers. Note figure 4, with illumination fibers 3 and separate detection fibers 4. Thus the statement in the declaration that energy "is reflected of backscattered into the illumination fiber" is at best misleading, since there is in fact no single individual fiber in which serves as both an illumination and a detection fiber. The declaration is based upon a confusion between a actual "fiber"; i.e. a single individual fiber, and a loose use the term "fiber" to represent what is actually a fiber bundle, i.e. a group of individual fibers. Further, the probe of Borsboom is disclosed as being usable in a mode in which the probe is actually in contact with the specimen being measured. As there is no single fiber which serves as both a illumination and detection fiber, it is physically impossible for, in such a use, there to be any light detected that is simple "returned from the surface of the sample." When all of the fibers are in contact with the sample, the only way for light to travel from an illumination fiber to a detection fiber is through the sample itself. This is explicitly states in Borsboom, column 2, lines 5-9, which includes the teaching that "[t]he light back-scattered in the center and within the diameter of

the illuminating beam, and hence has *traversed a short path in the translucent material*, is determined by the scattering characteristics of the material only."

[emphasis added]. Thus it is not true, as the declaration sets forth, that the light received by the detection fibers in the central fiber bundle "is predominately returned from the surface of the sample", and it is not true that Borsboom "has physically combined a reflectometer to measure backscatter with a classical single ring interactance probe to measure absorption", but rather detects light passing through the material along two different path lengths, with one being quite short.

Further, even were the characterization of the specific embodiment of Borsboom correct, the totality of the teaching of the reference would not be overcome. Borsboom includes a teaching (column 3, line 61 through column 4, line 1) that

"...a sensor head could be made in which a large number of juxtaposed optical fibers of diameter d is *arranged concentrically around a central optical fiber with an increasing radius*. Measurements made with such a sensor head gives a good picture of the amount of reflected light that has entered the *fibres arranged concentrically in rings*, and hence of *the light reflection as a function of the distance* from the light beamed into the material being investigated..." [emphasis added].

This at least clearly suggests placing fibers in rings (plural) concentrically around the central fiber at different distances.

The declaration argues that Borsboom "does not cite combining the two measurements in any way". It does not appear that independent claims 1, 6, 33 and 36 require "combining the two measurements;" rather claiming only a broad

"processing the signals with appropriate modeling techniques;" clearly Borsboom does not disclose detecting the plurality of different signals relating to different distances traveled though the sample without the clear intention of "processing" them, and it is clear that whatever processing would be done would be "appropriate." Thus the argument goes beyond what is claimed and thus is not relevant to what is actually claimed.

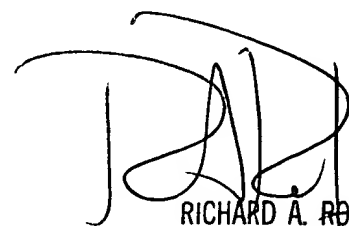
The declaration acknowledges that the references show what they are cited as showing what they were cited as showing, i.e. "to provide two optical paths defined by one aperture common to the two paths and separate apertures at the other ends of the two paths."

8. Papers related to this application may be submitted to Group 2500 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The fax number is (703) 308-7722.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. A. Rosenberger whose telephone number is (703) 308-4804.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0956.

R. A. Rosenberger
11 February 1997



RICHARD A. ROSENBERGER
EXAMINER
ART UNIT 255